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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/615,643	07/13/2000	Thomas L. Meredith	N-6089RSM	4680
23456	7590	11/23/2004	EXAMINER	
WADDEY & PATTERSON 414 UNION STREET, SUITE 2020 BANK OF AMERICA PLAZA NASHVILLE, TN 37219			PELLEGRINO, BRIAN E	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 11/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/615,643		MEREDITH, THOMAS L.	
	Examiner		Art Unit	
	Brian E Pellegrino		3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21-32 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 21-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,9,11,12,17,18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (5824078) in view of Scarborough (6616698). Nelson et al. disclose a method of forming a prosthesis using ground bone chips and placing them in a mold, col. 3, lines 18-39. Then a binder or cement is applied to harden or form a self-supporting, solid structure, such as an acetabular prosthesis. Nelson also discloses the use of applying pressure within the range of 14.7-30000 psi, col. 6, lines 4-6. It can be construed that the binder or cement is applied by injection or layering since it is applied in the mold and then forms a smooth layer of cement on one side of the prosthesis, col. 7, lines 52-54,65,66. Figs. 1-4 show die apparatus. However, Nelson does not explicitly disclose hydrating the bone composite with water. Scarborough teaches before implantation to hydrate the bone composite to provide some flexibility for shaping, but is self-supporting for use, col. 11, lines 58-64. It would have been obvious to one of ordinary skill in the art to use the step of hydrating with water as taught by Scarborough in Nelson's method of forming a bone composite such that it enables the composite to be shaped to the desired structure for use.

Claims 2-7,10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. '078 in view of Scarborough '698 as applied to claim 1 above, and further in view of Dowd et al. '813. Nelson et al. as modified by Scarborough is explained

supra. However, Nelson in view of Scarborough do not disclose the bone used as being cortical or the percentage of cortical tissue. Dowd also teaches the bone used can be cortical and demineralized, col. 3, lines 19,20, 26-29. Dowd additionally teaches binders can be applied before shaping or "molding" the implant, col. 4, lines 2-4. It would have been obvious to one of ordinary skill in the art to substitute types of bone and use cortical bone and the particle size within 125-850 microns as taught by Dowd with the method of Nelson as modified by Scarborough such that a more durable prosthesis can be formed. The benefits of using cortical over cancellous are obvious because it is known cortical is harder and has more structural strength.

Additionally, Nelson in view of Scarborough as modified by Dowd do not disclose the percentage of cortical bone in the bone tissue. It would have been an obvious matter of design choice to a person of ordinary skill in the art to use greater than 50% or up to 95% cortical bone tissue as the specific percentage used in the Nelson in view of Dowd composite because Applicant has not disclosed that any specific percent provides an advantage over another, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the percent of cortical bone as taught by Nelson in view of Dowd or the claimed greater than 50% or up to greater than 95% cortical bone because all percentages of cortical bone particles will still form a solid bone composite.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. '078 in view of Scarborough '698 as applied to claim 1 above, and further in view of Bonutti (6132472). Nelson as modified by Scarborough is explained supra.

However, Nelson in view of Scarborough do not disclose the addition of fibrin in the bone composite. Bonutti teaches that fibrin can added to bone material used as an implant, col. 3, lines 61-67. It would have been obvious to a person of ordinary skill in the art to use fibrin in the bone composite as taught by Bonutti in the Nelson as modified by Scarborough composite because fibrin is tacky and is capable of holding particles together.

Claims 8,32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. '078 in view of Scarborough '698 as applied to claim 1 above, and further in view of Glimcher et al. '502. Nelson as modified by Scarborough is explained supra. However, Nelson in view of Scarborough do not disclose the use of a particle size up to 850 microns. Glimcher et al. disclose a method of using bone tissue ground into a particle size between 125-850 microns, col. 7, lines 16-19. Glimcher also discloses a binder, such as a cyanoacrylate can be added with the bone particles, col. 11, lines 57-60. Glimcher additionally teaches the bone material acts as a structural support for bone formation, col. 11, lines 63-66. It would have been obvious to one of ordinary skill in the art to use the particle size as taught by Glimcher with the method of Nelson as modified by Scarborough such that it enhances the ability of the device to support new bone ingrowth. Cyanoacrylate is known for its good tissue bonding ability.

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. '078 in view of Scarborough '698 as applied to claim 1 above, and further in view of McDonnell et al. (5530037). Nelson as modified by Scarborough is explained supra. However, Nelson in view of Scarborough do not disclose the cement to be

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cyanoacrylate or the type of cyanoacrylate used. McDonnell et al. teach that cyanoacrylate adhesive is a good bonding binder for tissue materials and teaches the use of n-butyl type, col. 5, lines 4-9. It would have been obvious to a person of ordinary skill in the art to substitute cements and use n-butyl cyanoacrylate as a binder as taught by McDonnell in the method of Nelson because it has better bonding capabilities.

Regarding claim 16, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use long chain cyanoacrylates as the specific cyanoacrylate binder used in the method of Nelson as modified by Scarborough and McDonnell because Applicant has not disclosed that any specific cyanoacrylate provides an advantage over another, is used for a particular purpose, or solves a stated problem.

One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the cyanoacrylate taught by McDonnell or the claimed long chain cyanoacrylate binders because both types still function to hold together the bone particles. Additionally, McDonnell teaches short chain cyanoacrylates have some detrimental effects when used (col. 5, lines 9-11) thus the long chain would obviously be more advantageous.

Response to Arguments

Applicant's arguments with respect to claims 1 and 32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brian E. Pellegrino TC 3700, AU 3738
Primary Examiner

Brian E Pellegrino